DIAGNOSTIC ROLE OF GASTRIC ASPIRATION IN SPUTUM SMEAR NEGATIVE PULMONARY TUBERCULOSIS

GOVERNMENT HOSPITAL OF THORACIC MEDICINE,

TAMBARAM SANATORIUM

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CHENNAI-600 032

APRIL -2013

CERTIFICATE

This is to certify that the dissertation on **"DIAGNOSTIC ROLE OF GASTRIC ASPIRATION IN SPUTUM SMEAR NEGATIVE PULMONARY TUBERCULOSIS, GOVERNMENT HOSPITAL OF THORACIC MEDICINE, TAMBARAM SANATORIUM"** is a record of research work done by **DR.G.GAYATHRI** in partial fulfilment for M.D.(PULMONARY MEDICINE) Examination of the Tamilnadu, Dr.M.G.R.Medical University to be held in April 2013

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DECLARATION

I hereby declare that the dissertation entitled "**DIAGNOSTIC ROLE OF GASTRIC ASPIRATION IN SPUTUM SMEAR NEGATIVE PULMONARY TUBERCULOSIS, GOVERNMENT HOSPITAL OF THORACIC MEDICINE, TAMBARAM SANATORIUM"** submitted for the Degree of Doctor of Medicine in M.D., Degree Examination, Branch XVII, PULMONARY MEDICINE is my original work and the dissertation has not formed the basis for the award of any degree, diploma, associate ship, fellowship or similar other titles. It had not been submitted to any other university or Institution for the award of any degree or diploma.

Signature of the Scholar

Place: Chennai (Dr.G.Gayathri)

Date:

ACKNOWLEGEMENT

Language with all elaborations seems to be having limitation especially when it comes to expression of feelings. It is incapable of conveying in words all the emotions and feelings one wants to say.

It would take pages to acknowledge everyone who, in one way or another has provided me with assistance, but certain individuals deserve citation for their invaluable help.

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Finally it is endowment of spiritualism and remembrance of ALMIGHTY for all that I achieved.

CONTENTS

INSTITUTIONAL ETHICAL COMMITTEE,
STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work : Diagnostic Role of gastric aspiration in radiologically Suspected case of pulmonary tuberculosis among treated Pulmonary tuberculosis and fresh cases of pulmonary Tuberculosis (both groups being sputum negative)

Principal Investigator : Dr. G.Gayathri

Designation : PG in MD(TB&RD)

Department : Department of TB&RD
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The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 01.02.2011 at the Council Hall, Stanley Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate from the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.

MEMBER SECRETARY,
IEC, SMC, CHENNAI

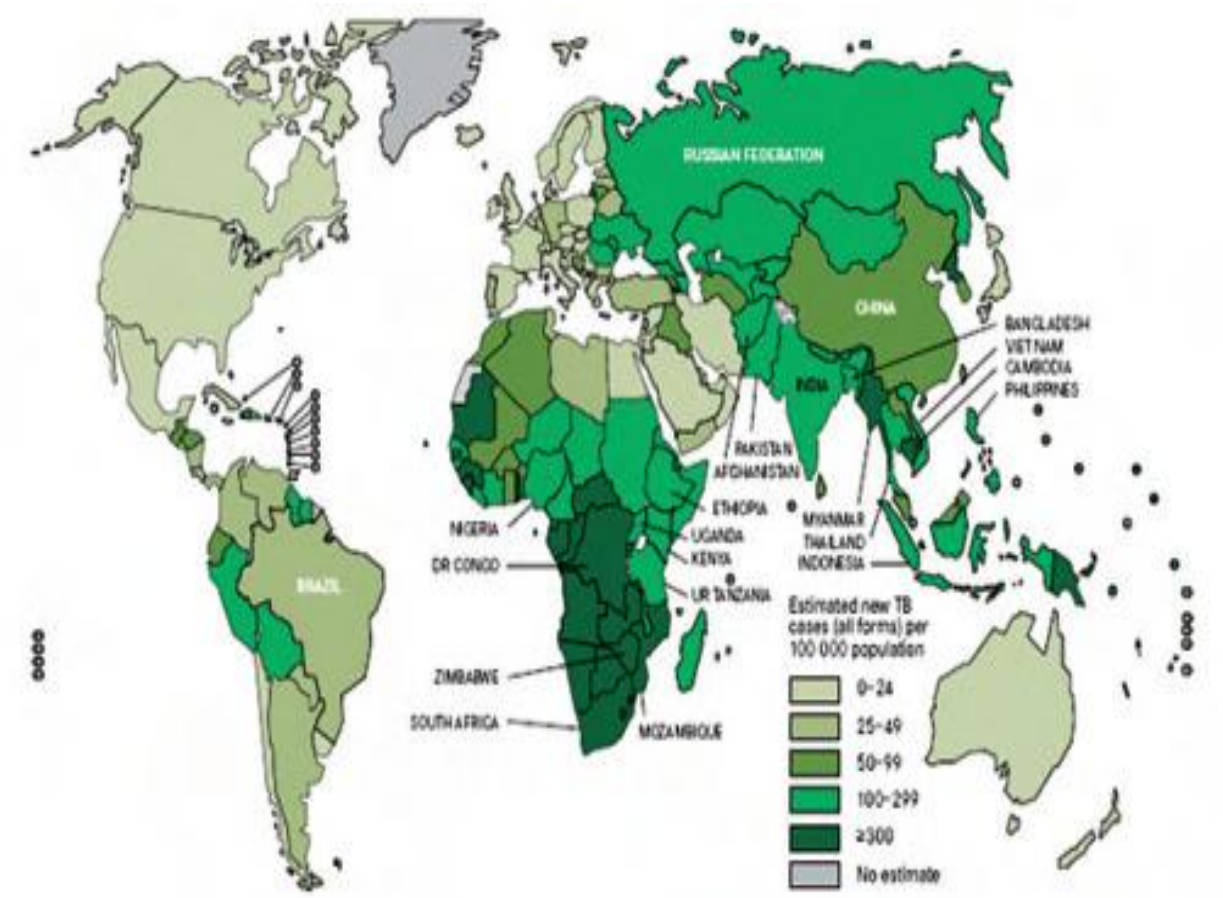
Our hospital is identified as one of the apex centre in catering treatment for huge some of population affected with chest diseases and HIV in Tamil Nadu.

Our centre is also identified as Centre of Excellence in HIV/TB care in the state. During our observation we identified that smear negative pulmonary tuberculosis getting treated in our centre contributes to about 52%.There are various modalities for obtaining representative sample other than sputum in these set of patients. There are studies documenting the role of gastric lavage in smear negative pulmonary tuberculosis especially children. There are only few studies identifying its role in adult patients. So we intended to study the diagnostic role of gastric aspirate in adult patients with pulmonary tuberculosis.

Disease burden

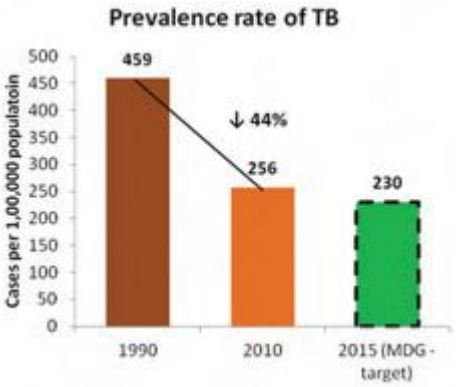
Tuberculosis is still one of the most deadly infectious diseases among developing countries like India with the mortality of around lives of over 2 million all over the world. Early diagnosis and treatment with effective chemotherapy in adequate dosage will cut down the morbidity and mortality [(1)].

Global map with latest update on the high burden countries with tuberculosis shows India having significant contribution[(2)] .



Not only the case load but in a recently conducted study by ICMR, it is identified that higher proportions of disease as well as MDR tuberculosis in three districts in India including **Tamil Nadu other two districts being Wardha and our capital state New Delhi[(3)].**So there is always a need to establish the diagnosis by various techniques and initiate the treatment as soon as possible.

The annual report of 2011-RNTCP gives the update on the prevalence and mortality rate .There is fall in the prevalence and mortality over 10 yrs and target has been set for better outcome [2]



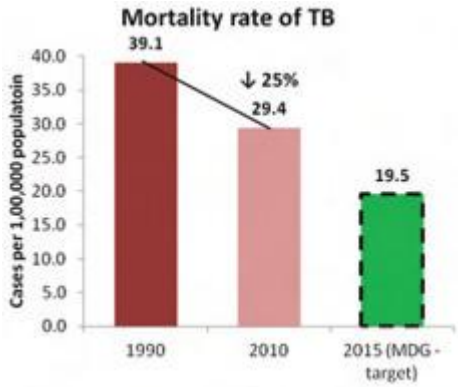
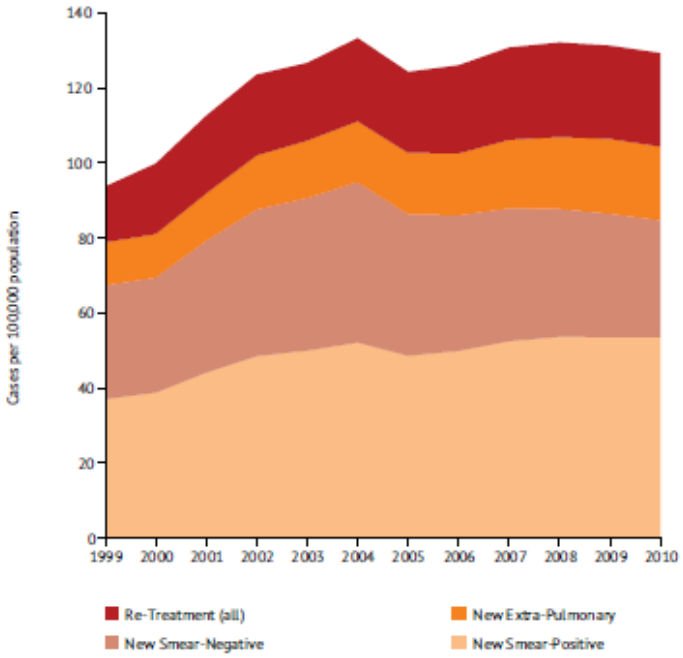


Figure 4: Total TB case notification, and the contribution of different types of TB cases, 1999–2010



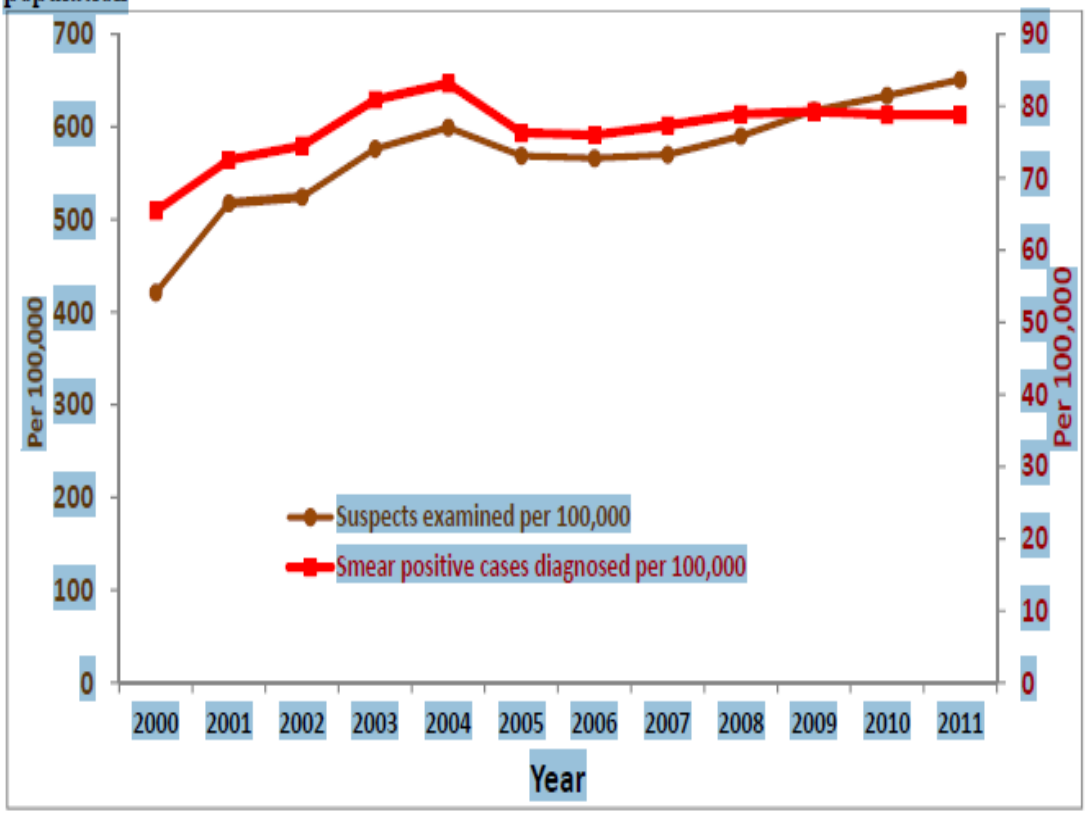
The table extracted from latest update of 10 yr old study elaborating the population of various category of patients with suspected pulmonary

tuberculosis [2]. From the table it is evident that smear negative pulmonary tuberculosis contributed to a sizable amount of population availing treatment.

A pulmonary tuberculosis suspect is a one with

Cough for more than 2weeks [2] associated with night sweats, weight loss, hemoptysis, low grade fever. All these TB suspects have to be subjected for sputum examination.

Figure 1: rate of TB suspect examined and smear positive TB cases diagnosed per 100,000 population



The problem of situation is that there a subset of population who present with symptoms other than cough and pulmonary tuberculosis has to be proved by varied techniques for the presence of acid fast bacilli either in smear or culture.

The TB infectiousness among smear negative pulmonary tuberculosis is around 11% as CDC identifies in a study [4].

There are various techniques for obtaining representative of pulmonary specimens for AFB smear and culture. Most common and prime sample to be collected in patients with pulmonary tuberculosis is sputum sample .There is certain criteria and instructions that have to be adhered to collect sputum sample. They are as follows.

Collection of sputum sample [2]:

- The sputum sample has to be collected in a sterile container which is wide mouthed avoiding contamination from external environment.
- The capacity of container should be 25 ml at least

- It should be a transparent container to observe the contents provided with the tight seal to avoid leakage

- The container should be provided with a label for identification

Sputum collection technique and instructions to patient for sputum submission and transportation of the sputum sample:

- Best sample will be a early morning sample before taking breakfast

- Specimen should be collected in open space away from other people to prevent environmental contamination.

- Ideally 2 specimens should be submitted where one sample should compulsorily early morning sample sent immediately to the laboratory as discrete specimens.

- The patient has to do deep breathing 2 to 3 times and to cough out deep from chest to collect sputum

- An ideal sputum sample should be at least 5 ml in volume which is thick, purulent in appearance.

- Sample should be transported to the lab as soon as possible. If there is delay, specimen should be stored in refrigerator or to be kept in a

cool place or can be mixed with cetyl pyridium chloride in 1 percent saline mixture.

The problem arise when we strongly suspect pulmonary tuberculosis but still obtain sputum for AFB to be negative and there are subset of population having no sputum production at all in spite of exhibiting symptoms of pulmonary tuberculosis.

The various other techniques employed to obtain representative samples are as follows:

INDUCED SPUTUM:

- For patients who presents with clinical suspicion of tuberculosis with no symptoms of sputum production can undergo induced sputum for AFB by inhaling hypertonic saline and submitting the sample for AFB smear and culture.

- There are possibilities of inducing bronchospasm in patients with underlying hypereactive airway disease. The sputum so submitted may be watery and resemble like saliva.

LARYNGEAL SWAB:

- This technique is adopted in children who are not able to produce sputum.
- This technique has been associated with greater chance of obtaining a contaminated specimen from upper airway commensals which are acid fast like non tuberculous mycobacteria actinomycocosis, nocardia.It may not be an ideal representative sample from lower respiratory tract.
- Further it is a cough invoking procedure which may be embarrassing procedure and greater chance of occupational exposure to health care professional

BRONCHOSCOPY:

- This technique has been employed for those who present inadequate sample or those who cannot produce sputum.Bronchoscopic specimens like brush wash and lavage fluid can be subjected for AFB staining and culture. The specimen obtained will be an ideal sample since we obtain the sample from the lesion if performed by experienced hands.

- This procedure needs technical expertise, patient preparation and hazardous to the bronchoscopist due to exposure to tubercle bacilli and equipment contamination demanding adequate sterilisation techniques to subject the patients for bronchoscopy.There are very few centres in Tamil Nadu performing bronchoscopy among paediatric age group also.

GASTRIC LAVAGE:

- Gastric lavage is a technique ideally performed in children as they have difficulty in expectorating the sputum. The concept of collecting gastric aspirate is that many of normal individuals tend to have micro aspiration in night time and hence gastric sample before consuming food is considered a representative sample for pulmonary tuberculosis.

- This is a simple, cost effective technique for obtaining representative sample for AFB.

- Gastric aspiration is a simple technique that can be performed by staff nurse and paramedical professionals. Unlike bronchoscopy, disposable forms of Ryle's tube can be used for every patient undergoing the procedure.

- Before undergoing complicated procedures like bronchoscopy, patients without sputum production can be subjected for gastric lavage.This technique can be of use in resource limited setting where sophisticated techniques like bronchoscopy are not available. The amount of exposure to tubercle bacilli is far less in gastric aspiration when compared to bronchoscopy.

- The difficulty in performing gastric aspirate is that patient needs to be prepared with overnight fasting

Under RNTCP, sputum smear for AFB is still the screening lab test in a suspect with pulmonary tuberculosis.

There are many causes for false negative AFB in sputum sample:

Inadequate sputum collection :

As mentioned previously patients are not thoroughly instructed as how to present sputum sample.

Improper storage of sputum specimens and staining methods:

Smear for AFB prepared should be prevented from sunlight and radiation, long period of storage for more than a week time will destroy AFB.

Improper selection from submitted sputum sample for slide preparation:

- While preparing slide sputum sample, the part which contains the thick purulent tenacious part of sputum containing necrotic material has to be separated by centrifugation and rest of sputum sample should be used for slide preparation.

- Staining should be done by proper techniques as per guidelines and reported. Either overheating the slide or adding too much of decolourising agent may spoil AFB bacilli.

Improper technique of examination of slide for AFB:

- Rapid reading of the slide stained as reading only few fields

- There are many such reasons where we treat in the clinical background in a pulmonary tuberculosis suspects even if they are sputum negative.

- Establishing the diagnosis in highly suspicious cases with alternative techniques is to be tried and to prove pulmonary tuberculosis.

In our centre sputum smear negative for AFB started on antituberculosis therapy amounts to around 52% amount to new cases and retreatment cases (rest contributes to extra pulmonary and smear positive cases).

Even though bronchoscopy which is more sophisticated alternative technique available for smear negative pulmonary tuberculosis is still available in our centre, we wanted to try gastric aspiration for AFB as it is a simple,economical,easy technique which can be performed doctors,paramedicals and staff also .Studies were published regarding the role of gastric aspirate in paediatric population. There are very few studies studying the role of a gastric aspirate in adult patients with pulmonary tuberculosis.

Culture techniques for diagnosis of pulmonary tuberculosis:

SOLID CULTURE TECHNIQUES:

Egg based medium:

Lowenstein Jensen medium/Pertragnini, Dorset

Blood based medium:

Tarshis

Serum-Loffler's medium

Potato-Pawlowsky

Liquid media:

Dubos, Middlebrook, Proskauer, Beck"s, Sula, Sauton.

Liquid media are employed for sensitivity testing, chemical analysis and preparation of antigens and vaccines.

Solid culture media:

Most common media used for identification is LJ medium. M.tuberculosis shows dry, rough, raised irregular colonies with a wrinkled surface. To start with creamy white later become yellowish or buff coloured.M.bovis shows flat, smooth, moist, white colonies.

In our study we have used LJ medium for inoculation.

The problem with LJ media is time constraint. It is not a preformed media instead constituents have to be procured and prepared with ideal concentration. The culture can be discarded as negative only after observing no growth after 8 weeks.

To overcome this and to study on extra pulmonary specimens, many rapid culture techniques have been developed.

BACTEC system:

This system is a radiometric system employing radio labelled carbon 14 liberated after decarboxylation of palmitic acid which is used as a substrate. This identifies M.tb within 5-7 days [5,6,7].

SEPTICHEK:

- Biphasic medium for diagnosis of tuberculosis having both liquid-Middle Brook and solid culture –agar on the other side in it.
- It helps identifying typical as well as atypical mycobacteria in the same culture tube.
- Higher diagnostic yield than conventional LJ medium
- This system can be applied for identifying mycobacterium tuberculosis in extra pulmonary specimens like gastric aspirate, urine, CSF, Ascites, synovial fluid etc [5,6,7].

MGIT: (Mycobacterium growth indicator tube)

It is non radiometric system using fluorochrome component with a oxygen sensor within it which produces a visible colour change for the detection of M.tb within 5-7 days [5,6,7].

ESP blood culture system:

BACTEC system identifies the organism by consumption of CO2 by MTB.But this system helps identifying organism by production of other gases. Blood culture obtained from suspects is read every 12-15 minutes for identifying visible changes in culture tubes [5,6,7].

Identification of mycobacterial species:

Chromatography:

The concept behind chromatography is based on the difference in the affinity of various substances for different media .This has been used in epidemiological studies .this helps in identifying the species and provides the results in two hours. This is a highly expensive technique. The method used mostly is high perfusion liquid chromatography [5,6,7].

TB PNA fish:

This is based on identifying the pseudo peptides binding site which are called PNA molecules. It helps in differentiating between typical and atypical mycobacterium.

MB/BacT:

It is a colorimetric system for detection of growth of mycobacteria even in blood cultures and detection of MTB in extra pulmonary specimens also. It uses a non radiometric system which identifies the organism based on CO2 that is constantly measured in the media and thus identifies the organism [5,6,7].

MODS: (Microscopic observation broth drug susceptibility testing)

It is a liquid culture technique using Middle brook medium for mycobacterial growth detection. This system is relatively in expensive which can be employed in developing countries.

Culture results can be obtained in 2weeks time.

The culture results are comparable with PCR and MGIT with the sensitivity of 92%

But the culture technique needs technical expertise and prescribed bio safety levels to be adopted for a considerable yield [5,6,7].

Gene Xpert:

- It is one of the rapid culture technique which speciate the Mycobacterium tuberculosis
- The culture method is so rapid that it can identify the species with viability within 2-3 hrs.
- It also identifies the rifampicin resistant MTB complex.
- At present in Tamil Nadu, it is available in only few centres like CMC, Vellore [5].

Nuclear amplification techniques:

These techniques use PCR for identification of bacterial DNA and amplify the sequence for identification of organism.

The problem with these techniques is that they are having a high sensitivity but at the expense of specificity that they identify the dead bacilli also [5].

Transcription mediated amplification:

It identifies the mycobacterium species by rRNA sequences in MTB complex which is detected by hybridisation protection assay with more than 95% sensitivity and specificity[5,6,7].

Ligase chain reaction:

It based on the technique of identifying MTB by using two flanking primers to a target DNA segment.

Genotypic studies:

Various other techniques for genotypic studies of MTB is available They are spoligotyping and DNA finger printing.

ANTIGEN DETECTION TEST:

Lipoarabinomannan urine test:

It detects LAM in the urine is a surrogate marker for mycobacterium tuberculosis infection. It is available in the form of dipstick test.

Flow through filter tests:

It detects Mycobacterium in sputum and body fluids by polyclonal antibody using flow through device.

Drug suspectibility testing:

It can be performed by direct and indirect methods.

Direct method

Digested and decontaminated samples are directly used for demonstration of AFB in stained smears. it is a true representative of bacillary population present in the specimen. test results are obtained in 3-4 weeks.

Indirect Method:

These tests are employed in smear negative with culture positive slides.

Three most commonly used method:

Absolute concentration method

Resistance ratio method

Proportion method.

Gastric aspiration was predominantly employed in children for suspicious cases of pulmonary tuberculosis. But the role of nasogastric aspiration in adults who are sick and bedridden and those who cannot expectorate was not much done in India.

Gastric aspiration is a simple procedure by which a nasogastric tube introduced through oral or nasal passage to recover the contents of gastric contents.

HISTORY

It is worth remembering the contribution by great laureates to the field of medicine for their new ideation and evolving new principles.

Since nasogastric tube was used as one of the tool in the study, we would like to add a note on John Ryle who invented nasogastric tube popularly called the RYLE"S TUBE

John Ryle:

He was a clinician at the Guy Hospital in London who invented nasogastric tube which is popularly called after his name "RYLE"S TUBE". He worked to understand the human in both external physical

and internal mental health as a combination. He has done study on pain analysis. He also explained the natural history of diseases caused by staphylococcus, E.Coli and streptococcal infection [8].

Robert Koch:

This great German physician who isolated first the bacilli called mycobacterium tuberculosis followed by which he developed tuberculin test. His contribution to the infectious diseases stops not just with tubercle bacilli. He was the first to isolate anthrax and cholera causing bacilli also. He also produced the BCG vaccine for immunisation against tubercle bacilli. He explained the four postulated for a germ or infectious agent called the KOCH postulates. He was honoured with Nobel Prize in 1905 for his contribution in the field of tuberculosis [9].

Recent advances in the field of tuberculosis:

Much of a focus in tuberculosis has been made in were diagnostic techniques in rapid diagnosis of tuberculosis.MGIT, septichek, gene xpert has been the latest additions in the field of diagnostics for tuberculosis. The test equivalent to the standard TST is recently being replaced by interferon gamma release assay which identifies TB infection in low endemic areas.

One of the landmark studies was done in 2004 by Dilek Saka et al[10] identifying the role of gastric aspiration in smear negative pulmonary tuberculosis obtained a 52% yield in smear negative suspected pulmonary tuberculosis. They emphasized in their study that gastric tube aspiration can a method of choice in smear negative pulmonary tuberculosis.

The study by Bahamann et al [11] demonstrated that the possibility of obtaining non tuberculous mycobacteria is also possible in gastric aspirate. But the possibility of NTM to grow in gastric aspirate is low.

They have also mentioned in their study that if gastric aspirate is positive for AFB then there is a high burden in respiratory tract in asymptomatic individuals.

The study conducted by Lubasi et al [12] comparing the yield by performing gastric lavage culture with conventional LJ medium and BACTEC system. They proved higher yield on performing a BACTEC rather than LJ medium culture with gastric lavage fluid. They have also added in their study that false positivity due to non tuberculous mycobacteria due to environmental contamination being very meagre.

In the study by Oguzhan et al [13], in patients who cannot expectorate had smear positivity and culture positivity by gastric aspirate was 61% and 30% respectively. In another group of smear negative pulmonary tuberculosis, BAL fluid for smear AFB and culture was 51% and 81%. Thus this study advocated gastric aspirate for those who cannot expectorate and BAL fluid for smear negative pulmonary tuberculosis.

Palme et al [14] investigated for comparison of sputum results with gastric aspirate among HIV positive and negative children. In their study they have suggested gastric aspirate for children less than 6 yrs and sputum sample for older children. With ongoing increase in HIV incidence, they attribute to say that the yield is low.

The study done at CMC, Vellore regarding the role of gastric aspirate in renal allograft transplant patients in the diagnosis of pulmonary tuberculosis by John jejuna et al [15], they showed a significant positivity when compared with BAL in renal transplants patients. They suggested gastric aspiration for AFB in suspects of pulmonary tuberculosis among renal transplant patients with fever, scanty expectoration and abnormal chest xray.

Chierukal et al [16] explored the validity of gastric aspiration in by comparing those with AFB positivity for PCR in smear negative

pulmonary tuberculosis. The overall sensitivity, specificity, positive predictive value, and negative predictive value of gastric aspirate examination by combined smear and PCR were 72, 58, 66, and 64%, respectively. They concluded gastric aspirate to be a useful tool for warranting antituberculosis therapy.

The study conducted by Rizvi et al [17] in Pakistan on adult patients who cannot expectorate, performing a gastric lavage and bronchoscopic wash concluded that 2 gastric washings has to be done for proving AFB while culture of bronchoscopic specimen was higher in yield but the yield was same in direct smear study for both gastric aspirate and bronchoscopic washing.

Brown et al [18] compared the yield from induced sputum, gastric aspirate and bronchoscopic washing. They performed the study in adults. They concluded in their study that 3 specimens of induced sputum yielded the same results as gastric washing. But the BAL did not increase the diagnostic sensitivity.

The study conducted by Mohan et al [19] about the yield on smear negative pulmonary tuberculosis by bronchoscopy.They submitted the bronchoscopic brush, wash and transbronchial biopsy for studying the culture, histology and PCR studies. They mentioned that the yield was

increased with bronchoscopy but the problem of disinfection, sterilisation and maintenance of equipment is a problem. They also mentioned about the occupational hazard in performing a bronchoscopy in a suspected case of pulmonary tuberculosis.

There are studies showing AFB which can be destroyed after application of local anaesthetic agent while performing a bronchoscopy.It may also contribute to low yield in bronchoscopic specimens for AFB.

AIM OF THE STUDY

- **T**o study the role of gastric aspiration in smear negative pulmonary tuberculosis in adult patients.

OBJECTIVES OF THE STUDY

- To study the diagnostic utility of gastric aspiration in sputum negative pulmonary tuberculosis by identifying gastric smear for AFB and culture.
- To compare the outcome among HIV positive and negative individuals
- To study how many were false negative due to improper techniques in sputum sample submission.
- To compare the radiological patterns with yield in gastric aspiration.
- To investigate the role of bronchoscopy in smears negative pulmonary tuberculosis.

Study group:

All patients with clinically suspected pulmonary tuberculosis and sputum smear negative for AFB (2 samples) based on their willingness to undergo the procedure after obtaining informed consent.

Inclusion criteria:

- Adult patients with age more than18 yrs
- Radiological and clinical suspicion of active pulmonary tuberculosis
- Sputum smear AFB (2 samples)-negative
- Those with no symptoms of sputum production.
- Very sick patients to submit sputum sample.

Exclusion criteria:

- Children
- Not willing to give consent
- Radiological inactive disease

IRB and ethical clearance:

The proposal to perform the study was presented in ethical committee meeting.

Study design was presented to the scientific committee and IRB, GHTM

After passing the proposal, acceptance obtained from above committee and study was initiated.

Study period:

The study period is started from November 2010-november 2012

Study subjects were classified into 3 groups

1. Those that have a sputum production with radio logically active lesion but sputum smear negative for AFB.

2. Those patients who are unconscious and very sick patients who cannot produce sputum are categorized into smear negative pulmonary tuberculosis.

3. Those who have a radiological significant lesion but they do not complain of sputum production at all.

Both HIV positive and HIV negative patients are subjected to gastric aspiration based on their acceptance randomly.

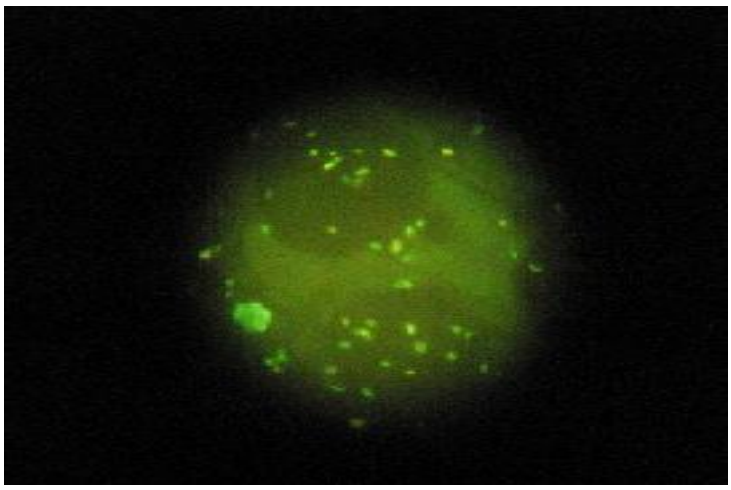
Sample size:

125

Material and methods:

In this study, gastric smear aspirated has been examined under fluorescent microscope and media for culture used is LJ media.

Fig 1-acid fast bacilli from gastric aspirate fluid appearing fluorescent staining with auramine and rhodamine (Image courtesy-Microbiology lab, GHTM)



Fluorescent microscope uses aura mine and rhodmaine dyes for staining of MTB.

Fixed smears are covered with 0.3% auramine and stained for 15 min and washed with 0.5% acid alcohol. Then the slide is stained with 0.1 % potassium permanganate.

DISADVANTAGES

The problem with the technique is highly expensive requires dark rooms and difficult to handle.

There are higher chance of false positive where the artefacts were take up the stain

The bulb which is one of the component parts needs to be changed from time to time and may be expensive to procure and repair.

Continuous power supply is needed with minimal voltage fluctuations for maintenance.

Advantages :

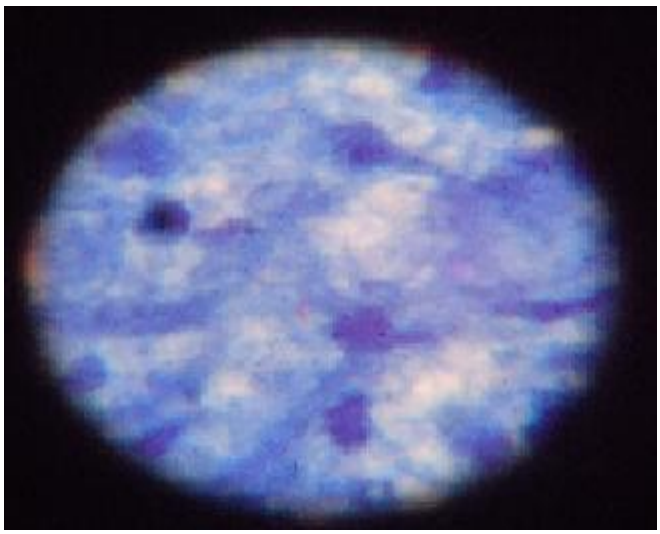
Field examined by fluorescent microscope is 0.34 mm2

The field examined under observation in conventional light microscope with oil immersion technique is 0.02mm2.

Fluorescent microscope offers shorter time than conventional microscopy after staining by Ziehl-Neelson staining.

One of the study quotes that a 100 smears /day examined can be compared with only 30-40 Zn stained smears

Fig-2: Acid fast bacilli from gastric aspirate fluid appearing as pink shaped rods against blue background in the conventional ZN staining.(Image courtesy-microbiology lab, GHTM)



The conventional ZN staining employs carbol fuschin as primary staining upon which 25%sulphuric acid is added following which decolourisation with 95%alchol is done .Counter stain with methylene blue imparts blue colour to the background for identification of slender slightly curved rods under oil immersion field.

There are other methods of staining like cold staining techniques like cold staining techniques called KINYON staining with higher concentration of basic fuschin and phenol

Fig-3-gastric aspirate incubated for AFB in conventional LJ slant medium showing buff colonies. (Image courtesy-microbiology lab, GHTM)

The most common used media is LJ media containing egg yolk which sustains the growth of MTB.

Green color to the media is given by malachite green which helps in identification of organism early. The media contains glycerol, aminoacids which provide the source of energy for growing

mycobacteria. This media supports the growth of both typical and atypical organisms.

Sample collection :

After obtaining informed consent from the patient, the patient is asked to be on overnight fasting at least for 8 hrs from previous day night.

Collection of sample :

The patient after applying lignocaine gel over nasal passage and over the naso gastric tube of appropriate size is taken.

Nasogastric tube is introduced and as soon as tube reached the gaster, position confirmed and at least 15-20 ml of gastric aspirate fluid collected in a sterile container without adding any fluid to it. If patient feels uncomfortable anytime, NG tube is withdrawn.

Transport of the sample:

The sample collected is labelled with a requisition slip and transported to the lab immediately. The transit time not more than 10 minutes.

Processing of the sample:

After obtaining the sample 4%NaOH is added to it for at least 10 min.The idea of adding NaOH is that it will destroy the bacteria other than mycobacterium, help to buffer the acidity of a gastric aspirate, also help to homogenise the sample.

Centrifugation is done at the rate of 3000 rpm/min for at least 5 minutes. After centrifugation supernatant is discarded and equal volume of normal saline is added to the sediment. Again the sample is subjected to centrifugation at the rate of 3000 rpm/min for 5 minutes. Similarly the supernatant is discarded and sediment is taken.

The sediment is then taken for preparation of smear at least 2 slides are prepared for each sample and examined under fluorescent microscope for acid fast bacilli

A part of sediment is taken for culture inoculation also. For each sample 2 tubes are used for inoculation. The conventional media used in our lab is Lowenstein Jensen medium which is egg based enriched medium.

The inoculum is incubated in LJ slant culture at 37 deg C for a period of at least 4-8 weeks.

Reading is taken every week. Most of the time colonies appear during 3-4 week. The contaminated sample with other bacteria most often showed varied growth and spoil the media and those samples are discarded. The sample is considered to have no growth after a wait period of at least 8 weeks after which the samples are discarded.

The culture positive specimens are those which grow colonies showing irregular raised dry, wrinkled colonies which are initially white to start with later appear with a buff colour.

There are various biochemical tests available to differentiate between typical and atypical mycobacteria but we are not provided with such tests in our lab.

Patients are then given education as how to produce good quality sputum and staff are also reinforced to give as supervised sputum sample. Before submitting the sputum sample, patients were asked to drink adequate water so that they are hydrated well.

Patients were also given a chance to undergo bronchoscopy. Based on the acceptance, patients were subjected for bronchoscopy and bronchoscopic brush and wash specimen were examined for AFB.

Patients data regarding their HIV status (if positive-CD4 count noted).Details among patients with history of contact with history of ATT was also noted.

Chest skia gram findings are noted:

In general, most common presentation of pulmonary tuberculosis is a cavity disease involving upper lobes. Patient may have sputum production if such a cavity is communicating with airway. In an immunocomprimised state like diabetes, HIV involvement of lesion is predominantly in lower lung field.

a. Nodules can be seen of variable size from micro nodules to macro nodules.

b. Exudative fluffy alveolo-acinar opacities can be seen in an active disease.

c. In post tuberculosis as a sequel various radiological patterns can be seen

d. Fibrosis with cavitations

e. Ectatic changes

f. Calcified nodules of variable size can be seen.

But there are no radiological shadows typical of pulmonary tuberculosis.

The atypical presentations are much more common in HIV diseased. Here the radiological patterns for pulmonary tuberculosis will be more often noted in lower lung fields and mediastinal or hilar adenopathy.More of HIV infected will also have co infection with other bacterial and fungal infections especially PCP pneumonia

Radiological grading of number of zones involved was noted. Lung zones for descriptive purpose are divided into 6 zones 3 zones-upper, middle, lower on each side. Thus in this study noting the number of lung zones involved, nature and type of lesion were done.

Patients with underlying co morbidities like diabetes mellitus, hypertension, chronic kidney disease, chronic liver disease were also noted.

ETHICAL JUSTIFICATION

The study was performed in patients who were willing for the procedure

Information form was given regarding the study

The consent was obtained in mother language

The study did not breach the medical ethics in anyway

Statistical analysis of data:

Data is analysed by using SPSS software. It is a descriptive analytical study.

Various parameters were compared with gastric aspirate yield.

P value calculated from Fischer exact T test, Pearson chi square test and statistical significance arrived.

In our study 165 patients were selected based on eligibility criteria. There were many drop outs as some of them does not want to undergo the procedure. During the procedure there were drop outs.

After obtaining the sample some of the specimens were contaminated and discarded. Ultimately we arrived at 125 subjects.

The categorisation of smear negative cases with clinical and radiological suspicion of pulmonary tuberculosis were made as follows

1. Sputum smear negative after submitting 2 samples for AFB(82)
2. No complaints of sputum production (26)
3. Unconscious patients (17)

In this study about 125 patients participated where 102(81%) males and 23(18%) females.

Table 1 Shows participation among sex group in the study

	Frequency	Percent	Valid Percent	Cumulative Percent
Male	102	81.6	81.6	81.6
Female	23	18.4	18.4	100.0
Total	125	100.0	100.0	

During the selection of patients both male and female were selected. We intended to take both male and female equally. There were more drop outs due to acceptance of procedure and many drop outs at the time of performing the procedure. Many of them were concurrently not willing for bronchoscopy among females.

Table-2 shows gastric culture positivity many sex group

			Gastric culture		
			Positive	Negative	Total
Sex	Male	Count	22	80	102
		% within sex	21.6%	78.4%	100.0%
	Female	Count	6	17	23
		% within sex	26.1%	73.9%	100.0%
Total		Count	28	97	125
		% within sex	22.4%	77.6%	100.0%
Fisher's Exact Test		.593	.411		

From the table, among the proportions of population studied, there is no statistical significance even when the percentage is almost equal in both the population as P value is 0.5 but there proportion is not

comparable because equal number of patients in both group participated in the study.

Table 3 shows classification of age group into various ranges

	Frequency	Percent
<25yrs	7	5.6
25-34	24	19.2
35-44	38	30.4
45-54	28	22.4
>=55yrs	28	22.4
Total	125	

From the table it seen that middle age group falling between class intervals 35-44 age group participated more among the various proportions. This may confirm the fact that tuberculosis is to be suspected more common among working class population.

Table 4 shows gastric culture positivity among various age group of population

			Gastric culture		
			Positive	Negative	Total
Age group	<25yrs	Count	5	2	7
		% within age group	71.4%	28.6%	100.0%
	25-34	Count	6	18	24
		% within age group	25.0%	75.0%	100.0%
	35-44	Count	6	32	38
		% within age group	15.8%	84.2%	100.0%
	45-54	Count	8	20	28
		% within age group	28.6%	71.4%	100.0%
	>=55yrs	Count	3	25	28
		% within age group	10.7%	89.3%	100.0%
Total		Count	28	97	125
		% within age group	22.4%	77.6%	100.0%
Pearson Chi-Square			13.542[a]	4	.009

The age group was sliced at range of 10 difference of interval for convinenience.From the table 3, it is seen that middle age group contributes to higher proportion of population. But from table 4 gastric culture positivity was high among younger age group of population for which the P value is significant (p value-0.009)

Table 5: explains proportions of population among smear negative Participated in various categories.

	Frequency	Percent
Smear negative	82	65.6
Unconscious	17	13.6
no_c/o_spm_prodn	26	20.8
Total	125	100.0

Among the various proportions major proportion falls under sputum smear negative group contributing to about 65%.

Table: 6 cross table showing gastric smear positivity among various study group

	Study groups		Gastric smear for AFB		
			Positive	Negative	Total
types	Smear negative	Count	16	66	82
		% within types	19.5%	80.5%	100.0 %
	Unconscious	Count	3	14	17
		% within types	17.6%	82.4%	100.0 %
	no_c/o_spm_prodn	Count	12	14	26
		% within types	46.2%	53.8%	100.0 %
Total		Count	31	94	125
		% within types	24.8%	75.2%	100.0 %
Pearson Chi – Square			8.053[a]	2	.018

This table compares the diagnostic yield of gastric aspirate fluid for AFB among various study groups. From this table it is inferred that among the various proportion of study group, there is statistical significance since the P value is<0.5.Eventhough the proportion of population was high among sputum smear negative group, percentage of positivity for AFB smear in gastric aspirate is more among those with group having no complaints of sputum production(46%).

Among the study group, smear for AFB from gastric aspirate fluid was approximately 24 % (31)while the gold standard which is gastric aspirate fluid cultured in LJ medium was 22%(28) positive. But gastric culture positivity is considered as gold standard for comparison throughout the description of results.

Table 7 shows gastric culture positivity among various categories of smear negative population

		Gastric culture positive		Total
		positive	negative	
Smear negative	Count	15	67	82
	% within types	18.3%	81.7%	100.0%
Unconscious	Count	2	15	17
	% within types	11.8%	88.2%	100.0%
no_c/o_spm_prodn	Count	11	15	26
	% within types	42.3%	57.7%	100.0%
Total	Count	28	97	125
	% within types	22.4%	77.6%	100.0%
Pearson Chi-Square		7.830[a]	2	.020

From the above table it is once again proved that as same as gastric smear that gastric aspirate culture is also high among the population with no sputum production category .This is evident from the P value because it is statistically significant(p value<0.5)

Those groups who are with altered mental status presenting with CNS disease contributes only a small percentage of population. Low yield in this group may be attributed to the reason that they may have a blunted cough reflex

For descriptive purpose radiological shadows are classified 5 different types both among new cases and sequel of pulmonary tuberculosis.

Table 8.Gastric culture positivity among based on the type of radiological shadows seen.

		Gastric culture		
		positive	negative	Total
Exudate		10	46	56
		17.9%	82.1%	100.0%
fibrocavity		7	22	29
		24.1%	75.9%	100.0%
cavity		4	13	17
		23.5%	76.5%	100.0%
consolidation		7	11	18
		38.9%	61.1%	100.0%
fibrosis/exudate		0	5	5
		.0%	100.0%	100.0%
Total		28	97	125
		22.4%	77.6%	100.0%
Pearson Chi-Square		4.986[a]	4	.289

Among the various proportions of radiological lesion there is a statistical significance ($p<0.2$) with high rate of culture positivity among those with a consolidation. Those presenting with a prior history of antituberculosis therapy either had evidence of fibro cavity with shift of trachea or suspecting a relapse had fluffy alveolar opacities on one zone with fibrosis and pull of trachea on other site. Among the treated cases, positivity was obtained among fibro cavity group.

Table 9 shows radiological involvement of various lesions depending on the number of lung zones involved

		Frequency	Percent
Valid	1	7	5.6
	2	52	41.6
	3	43	34.4
	4	18	14.4
	5	4	3.2
	6	1	.8

Chest xray is divided into upper, middle and lower lung zones on each side for descriptive purpose

From the above table it is inferred that most of patient had at least 2 0r 3 lung zones involved with the lesion either new cases or treated patients. The idea of collecting the lung zones involvement is that to arrive at whether many zones should be involved or even a small lesion with a cavity can show a positive culture.

Table 10 shows number of lung zones involved with comparison to gastric aspirate positivity in culture

			Gastric culture		
			positive	negative	Total
Lung zones	1	Count	0	7	7
		% within Lung zones	0%	100.0%	100.0%
	2	Count	11	41	52
		% within lung zones	21.2%	78.8%	100.0%
	3	Count	12	31	43
		% within lung zones	27.9%	72.1%	100.0%
	4	Count	4	14	18
		% within lung zones	22.2%	77.8%	100.0%
	5	Count	1	3	4
		% within lung zones	25.0%	75.0%	100.0%
	6	Count	0	1	1
		% within lung zones	.0%	100.0%	100.0%
Total		Count	28	97	125
Pearson Chi-Square			3.122[a]	5	.681

From the above table it is inferred that lung zones involved has no influence over gastric culture positivity because p value is not statistically significant (p value>0.6).Even a small cavity involving one zone or if many zones are involved does not influence gastric aspirate positivity and bacillary burden.

Table 11 shows the influence of previous treatment for pulmonary tuberculosis with gastric culture positivity

			Gastric culture		
			Positive	Negative	Total
Past history of anti tuberculosis therapy	Yes	Count	15	41	56
		% within prior history of ATT	26.8%	73.2%	100.0%
	No	Count	13	56	69
		% within prior history of ATT	18.8%	81.2%	100.0%
Total		Count	28	97	125
		% within prior history of ATT	22.4%	77.6%	100.0%
Fisher's Exact Test				.389	.199

From the above table it is seen that percentage of positivity is marginally more among treated cases. This does not carry much of statistical significance. This may be because many of them are defaulters of antituberculosis therapy as observed from our hospital. This may be reason for marginal high positivity among treated cases.

Table 12 shows HIV infected Vs Non HIV infected participated in the study

		Frequency	Percent
Valid	Positive	28	22.4
	Negative	97	77.6
	Total	125	100.0

Many of patients in our centre obtained treatment for HIV/TB mostly had an extra pulmonary presentation and hence the percentage may be low among HIV patients.

From above table it is inferred that only 22 percent population were HIV infected participated in the study.

Table 13 explains the diagnostic yield among HIV positive patients					
			Gastric culture		Total
			positive	negative	
HIV status	Positive	Count	3	25	28
		% within HIV status	10.7%	89.3%	100.0%
	Negative	Count	25	72	97
		% within HIV status	25.8%	74.2%	100.0%
Total		Count	28	97	125
		% within HIV status	22.4%	77.6%	100.0%
Fisher's Exact Test				.124	.072

Among HIV positive patients the yield was low -11 %(3) cases were positivity on culture in LJ medium when compared with HIV negative patients.

This is because there is varied radiological presentation in HIV disease. Most of presentation to our hospital is with advanced AIDS

presentation. Tuberculosis at this stage presents as a disseminated disease in the form of military tuberculosis or extra pulmonary nodal disease. This may be the reason for low yield among HIV positive individual. The population is not comparable with HIV negative group since the population participated with HIV positive disease is low. There are many overlapping presentation among various groups

Table 14 :cross table shows post gastric aspiration sputum for AFB

			Gastric culture		
			positive	negative	Total
Sputum for AFB after NG aspiration	Positive	Count	2	4	6
		% within Ryles_tube	33.3%	66.7%	100.0%
	Negative	Count	26	93	119
		% within Ryles_tube	21.8%	78.2%	100.0%
Total		Count	28	97	125
		% within Ryles_tube	22.4%	77.6%	100.0%
Fisher's Exact Test				.615	.405

From the table, sputum for AFB after subjecting the patients for gastric aspiration, patients were educated as how to give the sputum for AFB.The yield of sputum for AFB was 6 among these set of people,2 people have been already positivity in gastric aspirate.4 people had been proved positivity in sputum sample after subjecting them for AFB.

TABLE 15 shows those patients who were subjected for bronchoscopy and their yield.

			Bronchoscopy			
			Not willing	Positive for AFB	Negative for AFB	Total
Gastric culture	Positive	Count	24	0	4	28
		% gastric culture	85.7%	.0%	14.3%	100.0%
	Negative	Count	79	7	11	97
		% gastric culture	81.4%	7.2%	11.3%	100.0%
Total		Count	103	7	15	125
		% gastric culture	82.4%	5.6%	12.0%	100.0%
Pearson Chi-Square				2.226[a]	2	.329

Many of the patients who underwent gastric aspiration were not willing for bronchoscopy (103).Rest 22 of them among 125 were willing for bronchoscopy.Among them 7 cases were proved positive for AFB by bronchoscopic brush. These patients were negative on gastric aspirate

both by smear and culture. Whereas gastric aspirate identified 28 patients for AFB by culture. Though bronchoscopy can provide specimen exactly from suspected diseased segment, occupational exposure to AFB and other infectious agent through aerosol is very high while performing a bronchoscopy.Hence bronchoscopy is preferred only as a last resort in our study when there is a high clinical suspicion or doubt in our diagnosis.

Table 16 elaborates the role of co morbid illness in yield of gastric aspirate culture positivity other than HIV					
			Gastric culture positivity		
			positive	negative	Total
comorbid	No comorbities	Count	24	78	102
		% within comorbid	23.5%	76.5%	100.0%
	ckd	Count	1	4	
		% within comorbid	20.0%	80.0%	100.0%
	diabetes	Count	2	9	11
		% within comorbid	18.2%	81.8%	100.0%
	Liver disease	Count	0	3	3
		% within comorbid	.0%	100.0%	100.0%
	Bronchial asthma/steroid therapy	Count	1	3	4
		% within comorbid	25.0%	75.0%	100.0%
Total		Count	28	97	125
		% within comorbid	22.4%	77.6%	100.0%
Pearson Chi-Square			1.086[a]	4	.897

Co morbidities other than HIV were studied to assess if factors or disease state other than HIV is more common have smear negative status. Most of the studies quote diabetes as a common co morbid illness

associated with pulmonary tuberculosis. The conditions which are associated with pulmonary tuberculosis are smoking, alcoholism, HIV, malignancy, chronic liver disease ,chronic kidney disease and chronic steroid therapy [20,21]. But our study has shown that people only with diabetes contributed for only 18%.

Table 17 shows gastric aspirate positivity among those with positive history contact with a known TB pt in recent past.

			Gastric aspirate		
			positive	Negative	Total
contact	yes	Count	3	14	17
		% within contact	17.6%	82.4%	100.0%
	no	Count	25	83	108
		% within contact	23.1%	76.9%	100.0%
Total		Count	28	97	125
		% within contact	22.4%	77.6%	100.0%
Fisher's Exact Test				.761	.441

From the above table, many of our patients did not have a positive history of contact with a known sputum positive case.

Few among the contacts had a gastric aspirate positive. This may be because many of the cases who took part in study all are new cases.

Gastric aspiration for AFB though performed in children predominantly, our study emphasises the role of gastric aspiration in adults. There are many studies and articles on the role of gastric aspirate in children. The RED BOOK on tuberculosis emphasises further that best technique for obtaining in young children who complain of no sputum production or could not submit induced sputum sample, gastric aspirate to be a ideal sample. There are varied techniques available for obtaining a representative sample for proving pulmonary tuberculosis in adults

In our study 125 patients accepted to undergo gastric aspiration. Subjecting the patient for gastric aspiration required choosing of right candidate for the study criteria.

DEMOGRAPHIC FACTORS:

SEX:

In this study most of patients were male subjects presented with clinical features of pulmonary tuberculosis. This confirms the fact that the disease is more common among men perhaps due to contact from external source, immunocompromised state like chronic alcoholism. From the study, it is inferred that female patients were more reluctant to

undergo any invasive procedure whether gastric aspiration or bronchoscopy.Another reason for less female population presented is because of ignorance, inability to produce sputum, family problems, approach to health care centre presenting with diagnosis and treatment delay.

AGE:

From the table-(3,4) it is inferred that the set of people suspected to have pulmonary tuberculosis were falling under middle age group (35-44), proving that pulmonary tuberculosis is a disease of middle age working class population. This data addresses the need to suspect the people of middle age group with respiratory complaints for pulmonary tuberculosis. On contrary, were able to prove by LJ culture with significant growth for tubercle bacilli among people with age group <25yrs. This is because many of them expectorate the saliva rather sputum for testing or they are very sick to submit the sample for examination.

GASTRIC ASPIRATE AND STUDY CATEGORIES:

In this study, population among the study groups were divided into 3 categories .Gastric aspirate positivity was high among population with no sputum production group. This may be because most of this population tend to swallow the sputum. This can also be explained because many of patients have an underlying COPD with respiratory muscle fatiguability to produce sputum. Many of them will have an extensive disease with cachexia and sick finding difficult to expectorate. Bahaumann et al [(11)] in their study concludes that gastric smear for AFB though not sensitive is highly specific to initiate treatment on antituberculosis therapy. He also emphasis here that if gastric aspirate smear is positive for AFB it indicates that the bacillary load is enormous

GASTRIC ASPIRATE AND ANTITUBERCULOSIS THERAPY:

The gastric aspirate smear for AFB and culture positivity does not seem to be influenced by prior episode of antituberculosis therapy. The yield appears to be almost equal among both treated cases for pulmonary tuberculosis and also among new case suspects.

RADIOLOGY AND GASTRIC ASPIRATE:

Radiological suspicion of pulmonary tuberculosis based on type of lesion adds to the fact from our study that though exudative lesion had more common suspicion, gastric culture positivity was more among people with consolidation like picture. Dooley et al [22, 23] identified that there is delay in the diagnosis of pulmonary tuberculosis by at least 16 days to start on anti tuberculosis therapy in suspected cases of community acquired pneumonia. He also adds in his study that many of the patients with suspected community acquired pneumonia are exposed to respiratory fluoroquinolone before starting them on conventional antituberculosis therapy. This may lead to emergence of fluoroquiolone resistant strains of pulmonary tuberculosis. This may be one of the reasons for sputum smear negativity due to short course of fluroquinolone.This also emphasises our need to establish the diagnosis of pulmonary tuberculosis and decide on ATT as soon as possible. Number of zones in the chest skiagram involved does not seem to influence the gastric smear positivity. There is no statistical significance to number of zones involved even if the >5 or<2 involved.

HIV DISEASE AND GASTRIC ASPIRATE:

There were various group of people participated under the 3 categories as required under study criteria among HIV diseased population (23%).But the population could not be compared with those of HIV negative (77%).The yield among HIV positive was around 10 % when compared with HIV negative population .But since HIV positive and negative were not of equal proportion we could not really comment on the yield as population size is not comparable. It is also worth noting that HIV diseased state is a paucibacillary type and stage 4 WHO stage with low CD4 count where extra pulmonary forms of tuberculosis,miliary forms of disseminated disease is more common[24].These may be reasons for low yield among HIV positive individuals. Radiological description of tuberculosis in HIV infected performed in our centre by C.N.Deivanayagam et al [25] showed that most common infection is tuberculosis presenting both as cavitory and non cavitory diseases. Next site most common is extra nodal is hilar adenopathy.They also quoted in their study that there are lot of atypical with subtle changes and overlapping manifestations in xray which makes the diagnose more difficult.

POST GASTRIC ASPIRATE SPUTUM SPECIMEN:

The study population were educated after having underwent a gastric aspiration to submit sputum for AFB.This time they were all hydrated well and asked to give thick tenacious sputum as soon as getting up from the bed and submit he sputum for AFB.From the table it is inferred that there are as small subset of population who among the smear negative category who were not able to give good quality sputum when educated and hydrated well were able to prove positive by conventional sputum smear techinique.This emphasis the need to conduct training session for health care professionals regarding good quality adequate sample so that they can help in avoiding the false negative sputum samples.

BRONCHOSCOPY AND GASTRIC ASPIRATE:

Bronchoscopy is a invasive procedure needing technical expertise. We need to prepare the patient, constant monitoring during the procedure and chance of equipment related contamination is possible when performing a bronchoscopy.The patients acceptance and cooperation to undergo bronchoscopy also is less among our study population because all who underwent gastric aspiration were not ready to undergo bronchoscopy.

More over gastric aspirate can be performed by staff and paramedics as compared to bronchoscopy which demands technical assistance.

There is a occupational hazard for the health care professional engaged in bronchoscopy suite as bronchoscopy is a cough inducing procedure and chance of health are related nosocomial infection.

There are studies quoted saying that the AFB may get destroyed while using local anaesthetic agent and spray during bronchoscopy and this may reduce the detection rate.

Oguzhan et al [13] quotes as per the findings of his study that gastric lavage can be proposed as a procedure of choice among patients with no sputum production group and bronchoscopy can be advocated for patients with smear negative for AFB.

Limitations:

- Diagnostic yield would have been more if 3 subsequent gastric washings were performed. But in this study only once gastric aspiration was performed because of patient compliance.

- There are chances obtaining atypical organisms since the specimen is gastric aspirate with environmental mycobacteria.The biochemical tests has to be performed to confirm the atypical organisms.

- Amount of sample collected here in this study from gastric aspirate was minimum of 10 ml .The yield would have been even more if gastric fluid has been thoroughly aspirated. The collection of sample also depends on patient's compliance also.

- The reason for higher yield in gastric smear (24%) for AFB when compared with culture (22%) may be because of higher false positivity in fluorescent microscopy(higher sensitivity)

- There were some of the specimens which were discarded as contaminated during incubation. This may be because the media is not a preformed one and ingredients are procured and processed for

preparation so there are chances of contamination and missing growth in some expected samples.

- The culture studies performed in this study on conventional LJ medium. Rapid culture techniques may help in starting on treatment rapidly.Furthur studies have to be done on gastric aspirate with rapid culture techniques.

From this study, gastric aspirate for smear positivity among sputum smear negative pulmonary tuberculosis was 24% and gastric culture positivity was 22%.

Gastric aspirate for AFB smear and culture can be used as a tool in diagnosis of pulmonary tuberculosis in patients who cannot submit sputum and patients who are smear negative as suggested by the study.

Gastric aspirate performed on 3 consecutive days may improve the diagnostic yield.

Gastric aspirate performed among HIV positive patients was only 10%.This may be because HIV infected in this institution had extra pulmonary forms and disseminated tuberculosis rather than pulmonary presentation.

In this study it is also identified that false negative sputum smear samples were also present as some of the cases had post gastric aspirate sputum smear positivivity .This may be because many of patients who had submitted saliva or they were not hydrated properly to bring out good quality sputum. Our study also emphasises the need that all patients who are submitting the sputum sample for AFB should be educated and

emphasised on sputum sample submission by doctors ,staff and paramedical, social workers and counsellors as how, when to collect and produce sputum sample or information in the form of pamphlets or display charts. This we suggest that may help to avoid false negatives in sputum samples.

Gastric aspirate positivity in culture had a high yield among chest xray with suspected pulmonary tuberculosis with consolidation pattern(38%).There is practice of prescribing fluoroquinolone for community acquired pneumonia in private. The patients seeking treatment in a tertiary care centre are not naïve population .Many of them would have had treatment and exposed to fluoroqunilones before presenting to us and hence these patients are at the risk of developing fluroquinolone resistant pulmonary tuberculosis.

DOTS program in India is functioning at the level of primary health centre where sophisticated techniques like bronchoscopy are not available, patient presenting with no sputum under suspicion of tuberculosis, gastric aspirate can be performed as a diagnostic technique which is a simple outpatient procedure. The sample can be subjected for AFB smear study in the lab immediately. The procedure can be performed by trained health care professional like staff nurses unlike

bronchoscopy which needs to performed by trained bronchoscopist with constant monitoring.

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PROFORMA

NAME: AGE:

SEX: OCCUPATION:

EDUCATIONAL STATUS:

HISTORY

PRESENTING COMPLAINTS:

S.NO	Symptoms	Present/absent	duration
1.	Cough		
2.	Sputum		
3.	Breathlessness		
4.	Haemoptysis		
5.	Fever		
6.	Chest pain		
7.	Loss of weight		
8.	Loss of appetite		
9.	Nausea &vomiting		

10.	Other complaints		

PAST HISTORY:

S.NO	DISEASES	DURATION	DRUGS TAKEN
1.	Pulmonary/extra pulmonary tuberculosis		
2.	Ischemic heart disease		
3.	Diabetes mellitus (type ½)		
4.	Bronchial asthma		
5.	Immunodeficiency		

PERSONAL HISTORY:

Diet

Bladder and bowel habits

Smoker-beedi/cigar/cigarette

Betel nut chewer

Alcohol

CONTACT HISTORY:

H/O of contact with known TB pt in his/her house/neighbourhood/workplace

yes	no	Duration of exposure/ATT

FAMILY HISTORY:

H/O DM/SHT/IHD/BA among family members

H/O of pulmonary /extrapulmonary tuberculosis among family members.

Duration of ATT

GENERAL EXAMINATION

Built/nourishment:

Pallor:

Jaundice:

Clubbing:

Pedal oedema:

Significant lymphenopathy:

VITALS

Height: weight: Temperature:

BP: RR: Pulse rate: SpO2:

SYSTEMIC EXAMINATION

CARDIOVASCULAR SYSTEM:

RESPIRATORY SYSTEM:

ABDOMEN:

CENTRAL NERVOUS SYSTEM:

DIAGNOSIS

INVESTIGATIONS

Sputum examination:

Sputum smear for AFB(Fluorescent microscopy)	Sample A:	Sample B:

Gastric aspirate examination:

Gastric aspirate smear for AFB(Fluorescent microscopy)	
Gastric aspirate culture for AFB(LJ medium)	

Post gastric aspiration sputum for AFB

Sputum sample C	Sputum sample D

Imaging

Chest xray findings

Number of zones involved	
Type of lesion	

CT thorax:

USG abdomen/chest:

Blood investigations:

Hb%: TC/DC/ESR:

Blood urea: serum creatinine:

Random blood sugar:

Fasting blood sugar/post prandial blood sugar:

CD4 count (HIV):

Urine investigations

Urine routine –albumin/sugar/deposits

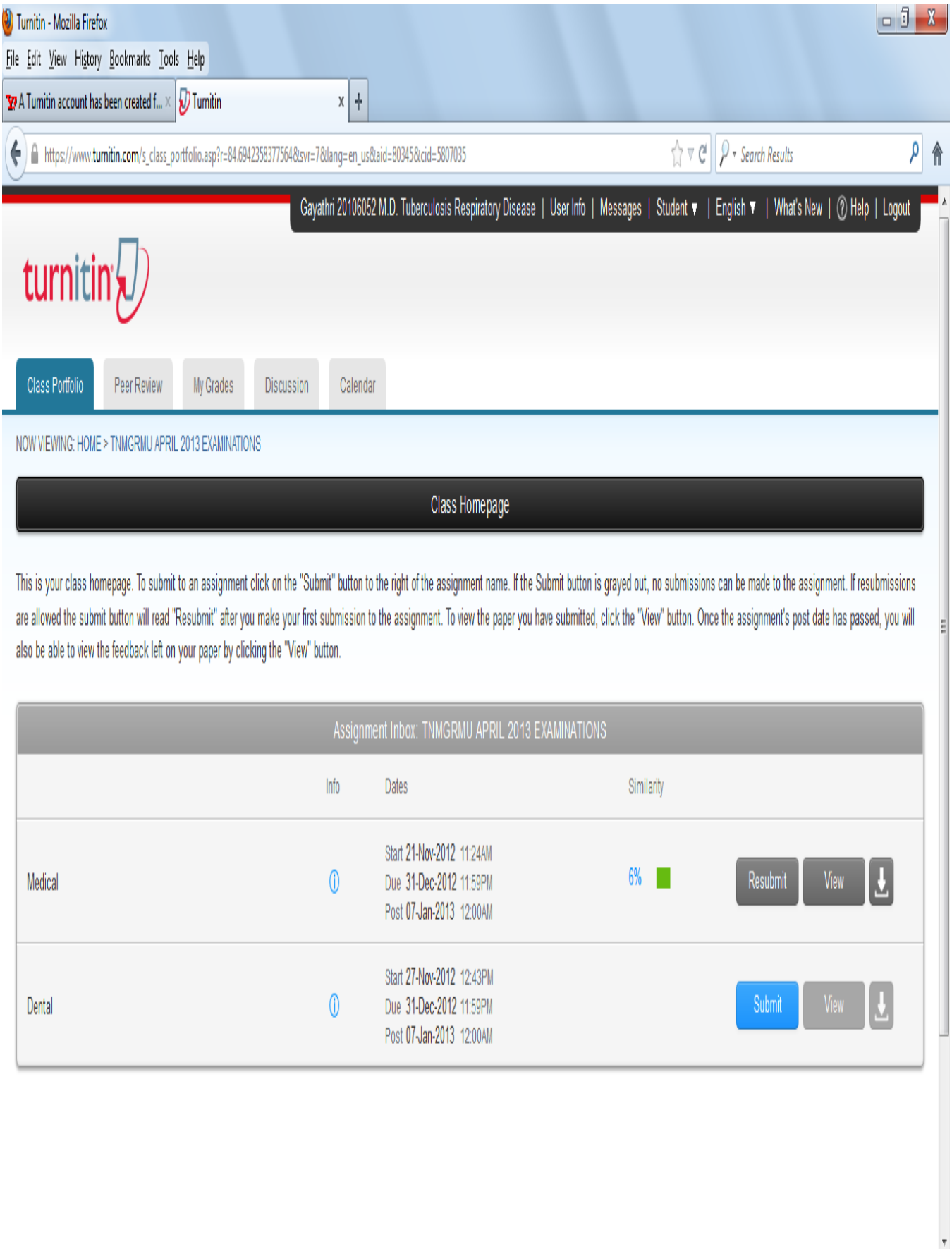
Urine for ketone:

Urine for bile salts/pigments:

Other investigations:

ECG:

Treatment given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DIAGNOSTIC ROLE OF GASTRIC ASPIRATION IN SPUTUM

SMEAR NEGATIVE PULMONARY TUBERCULOSIS

GOVERNEMNENT HOSPITAL THORACIC MEDICINE,

TAMBARAM SANATORIUM

Dissertation submitted In Partial Fulfilment of the

Requirements for the Degree of

DOCTOR OF MEDICINE

PULMONARY MEDICINE

Branch - XVII

2010-2013

DEPARTMENT OF PULMONARY MEDICINE

Government Stanley Medical College & Hospital

Chennai-600 001

தகவல் படிவம்

நுண்கதிர் படத்தில் காச நோய்க்கான அறிகுறி இருந்தும் சளியில் அந்நோய்க்கான கிருமிகளைக் கண்டறிய முடியாத ஐயப்பாடு ஏற்பட்டுள்ள நிலையில் காசநோய்க்கிருமியைக் கண்டறிவதற்கான ஓர் ஆய்வு.

உங்களுக்கு காசநோய்க்கான அறிகுறிகள் தென்படுகின்றன. மேலும் நுண்கதிர் படத்தில் காசநோய்க்கான அறிகுறிகள் தெரிய வந்துள்ளது. ஆனால் சளியின் மாதிரி பரிசோதனையில் காசநோய்க்கான கிருமிகளை கண்டறிய முடியவில்லை . எனவே செயற்கைக் குழாயை மூக்கின் வழியாக இரைப்பையில் செலுத்தி நீரை மாதிரிக்கு எடுத்து பகுப்பாய்வு கூடத்தில் பரிசோதனை செய்து உறுதி செய்யலாம் என நினைக்கிறேன்.

இதன் மூலம் நோயை அறிந்து கொண்டு மருத்துவ சிகிச்சையை மேலும் மேம்படுத்துவதற்காக மேற் கொள்ளப்பட உள்ள ஆய்வு.

தாங்கள் விரும்பினால் மருத்துவ ஆய்விலிருந்து எப்பொழுது வேண்டுமானாலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நீங்கள் ஆய்விலிருந்து விலகிக் கொள்ளலாம்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களும் பரிசோதனை முடிவுகளும் தங்களின் ஒப்புதலின் மூலம் மட்டுமே மருத்துவ ஆய்வில் பயன்படுத்தப்படும்.

ஆய்வாளர் கையொப்பம்:

ஆய்வாளரின் பெயர்:

இடம் :

நாள் :

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு

நுண்கதிர் படத்தில் காச நோய்க்கான அறிகுறி இருந்தும் சளியில் அந்நோய்க்கான கிருமிகளைக் கண்டறிய முடியாத ஐயப்பாடு ஏற்பட்டுள்ள நிலையில் காசநோய்க்கிருமியைக் கண்டறிவதற்கான ஓர் ஆய்வு

ஆராய்ச்சி நிலையம் : அரசு நெஞ்சக நோய் மருத்துவமனை
தாம்பரம், சானடோரியம், சென்னை-600 047.

பங்கு பெறுபவரின் பெயர் :

பங்கு பெறுபவரின் :

பங்கு பெறுபவர் இதனை (√) குறிக்கவும்

- மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்களை எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களைக் கேட்கவும், அதற்கான தகுந்தவிளக்கங்களைப் பெறவும் வாய்ப்பளிக்கப்பட்டது. [ ]

- நான் இவ்வாய்வில் தன்னிச்சையாகத்தான் பங்கேற்க்கிறேன், எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகிக் கொள்ளலாம் என அறிந்துக் கொண்டேன். [ ]

- இந்த ஆய்வின் சம்மந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும். இந்த ஆய்வில் பங்கு பெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொன்கிறேன். நான் ஆய்விலிருந்து விலக்கிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன். [ ]

- இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும் பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும் அதை பிரசுரிக்கவும் என முழு மனதுடன் சம்மதிக்கிறேன். [ ]

- இந்த ஆய்வில் என்னை உட்படுத்தி கொள்ள ஒப்புக்கொள்கிறேன், எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின்படி, நடந்துக் கொள்வதுடன் இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறான நோய்குறி தென்பட்டாலோ அதை உடனே மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதியளிக்கிறேன். [ ]

- இந்த ஆய்வில் எனது நுண்கதிர் படம் சளி, சீறுநீர், இரைப்பை நீர், பரிசோதனை செய்துக்கொள்ள நான் முழுமனதுடன் சம்மதிக்கிறேள். [ ]

பங்கேற்பவரின் கையொப்பம் _____ இடம் _____ தேதி

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம் _____

ஆய்வாளரின் பெயர் மற்றும் விவாசம் _____

ஆய்வாளரின் கையொப்பம் _____ இடம் _____ தேதி

CONSENT FORM

1) I agree to participate in the study entitled,

"DIAGNOSTIC ROLE OF GASTRIC ASPIRATION IN PATIENTS WHOSE SPUTUM ARE NEGATIVE WITH RADIOLOGICAL SUSPICION OF PULMONARY TUBERCULOSIS"

2) I confirm that i have been told about this study to be conducted in my mother tongue and have had the opportunity to ask questions .

3) I understand that the participation is voluntary and I may refuse to participate at any time without giving reasons and without affecting my benefits.

4) I agree not to restrict the use of any data or results that may arise from this study.

Name of the participant: Sign/ thumbprint:

Sign of the investigator:

name	age	sex	op number	types	GASTRIC SMEAR	gastric culture	Prior history of ATT	type of lesion	Number lung zones involved	hiv s tatus	Sputum after ryle tube	Como rbid condi tins	Bron chos copy	Con tact
mayan	55	M	4152062011	3	1	1	2	1	4	2	1	1	1	2
Anandan	41	M	4080662011	1	1	1	1	2	3	2	2	0	1	2
Swaminathan	51	M	23072011	1	2	2	2	2	6	2	2	0	1	2
Sugumar	46	M	1418042011	3	2	2	2	1	5	2	2	1	1	2
Subramani	49	M	1082072011	3	2	2	2	3	1	2	2	1	2	2
ganeshkumar	26	M	6876072011	3	2	2	1	2	3	2	2	0	1	2
raghu	28	M	2540072011	3	1	1	2	1	3	2	2	0	1	2
kala	28	F	1144072011	1	2	2	1	5	4	2	2	0	1	1
Hariharan	25	M	3505072011	3	1	1	2	1	3	2	2	0	1	2
perumal	55	M	3414072011	3	2	2	1	2	2	1	2	3	1	2
Manickam	38	M	205082011	3	2	2	1	2	5	2	2	0	1	2
raji	49	M	3676072011	3	2	2	1	4	4	2	2	0	1	1
siddiq	16	M	1068082011	3	2	2	1	2	3	2	2	0	1	2
Arumugam	30	M	2550012011	1	2	2	1	2	3	2	2	2	1	2
kali	55	M	1265082011	1	2	2	1	2	2	2	2	2	1	2
prathap	21	M	2254082011	1	1	1	2	4	2	2	1	0	1	1
ramar	21	M	2302082011	1	2	2	2	2	3	2	2	0	1	2
thangaraj	45	M	2253082011	1	1	1	1	1	5	2	2	0	1	2
rajarajan	19	M	2855082011	1	1	1	2	4	4	2	2	0	1	1
balan	59	M	114092011	1	2	2	1	1	4	1	2	0	1	2
balammal	50	F	2640052011	1	2	2	1	5	3	2	2	2	1	2
Govindammal	43	F	4409122007	3	2	2	1	1	5	1	2	0	2	2
ramasamy	52	M	636092011	1	2	2	2	4	4	2	2	0	1	2
kanniyapan	68	M	2015062011	2	2	2	1	3	2	2	2	0	1	2
krishnamoorthy	43	M	2718092011	2	2	2	2	1	2	1	2	0	1	2
sampath	36	M	2154092011	1	1	1	1	2	2	1	2	0	1	2
Ramu	43	M	2421092011	2	1	1	1	2	3	2	2	0	1	2
vasudevan	55	M	783092011	1	2	2	2	4	4	2	2	0	2	2
saroja	50	F	791092011	1	1	1	1	3	2	2	2	0	1	2
Ravichandran	40	M	3589082011	1	2	2	1	1	2	1	2	0	1	2
Mannankati	70	M	335102011	1	1	1	1	2	3	2	2	0	1	2
wilson	48	M	3469092011	1	2	2	1	2	2	2	2	0	1	2
govindasamy	63	M	3983092011	3	2	2	2	3	1	2	2	0	2	2
Nanitha	45	F	1007102011	2	2	2	2	1	4	1	2	3	1	2
gokilammal	52	F	28111996	1	2	2	2	3	3	2	2	0	1	2
ramanathan	49	M	668102011	2	2	2	1	1	2	1	2	0	1	2
Muthusamy	62	M	1036102011	1	2	2	2	1	1	2	2	0	1	2
ravi	40	M	1145102011	1	2	2	2	3	3	2	2	0	1	2
sekar	34	M	4828092008	1	2	2	2	1	2	2	2	0	2	1
velumani	40	M	166902011	1	2	2	2	3	2	2	2	0	3	2
kuppusamy	60	M	21771102011	1	2	2	1	1	3	1	2	0	3	2
Patchyappan	44	m	2076102011	2	2	2	1	4	2	1	2	0	3	1
selvam	36	M	1054082011	1	1	1	2	4	3	1	2	0	3	2
mariamma	39	F	4002052007	1	2	2	1	1	2	1	2	0	1	2
velayudham	49	M	2899102011	1	2	2	2	3	3	2	2	0	1	2
kannadasan	35	M	2692012011	2	1	2	2	1	4	2	2	0	1	2
perumal	53	M	6659082003	1	2	2	1	5	4	2	2	0	1	1

krishnamoorthy	61	m	65112011	1	2	2	2	4	3	2	2	0	3	2
ponnusamy	55	M	2738122005	2	2	2	1	2	2	2	2	0	3	2
rajesh	25	M	788112011	1	2	2	2	1	3	2	2	0	2	1
anthony yesu	29	M	4438012010	1	2	2	1	3	2	2	2	0	1	2
balakrshnan	29	M	758052008	1	2	2	1	1	4	1	2	0	1	2
praveena	23	F	1099112011	1	1	1	1	4	3	2	2	0	1	2
srinivasan	36	M	1475112010	3	1	1	2	2	3	2	2	0	1	2
sampath	41	M	5072011	1	2	2	1	2	3	2	2	1	1	2
Thangaraj	41	M	1665082011	1	2	2	1	1	2	2	2	2	1	2
pavithra	16	F	2350042011	3	1	1	2	1	2	2	2	0	1	2
ramesh	38	M	3543112011	1	2	2	2	1	2	1	2	4	2	2
rajendran	34	M	78122011	1	1	1	2	3	2	2	2	0	1	2
ramadoss	56	M	108122011	1	2	2	2	1	3	2	2	0	1	1
raja	34	M	958012005	1	1	2	2	1	2	2	2	0	3	2
Chandran	57	M	876122011	3	1	1	1	2	4	2	2	4	3	2
Jayashankar	27	M	935122011	1	1	1	1	3	3	2	2	0	3	2
Chinnaya	60	M	433122011	1	2	2	1	1	2	2	2	0	3	2
Ramesh	35	M	3869012011	1	2	2	2	1	2	2	2	0	1	2
Rajappan	38	M	317122011	3	2	2	2	2	4	2	2	0	1	2
adhilingam	30	M	317122011	2	2	2	2	1	2	1	2	0	1	2
Sivakumar	40	M	1038102011	2	2	2	2	1	2	1	2	0	1	2
Anbalagan	43	M	171062003	1	2	2	2	1	4	2	2	2	1	2
Chandran	70	M	2252122011	1	2	2	2	4	2	2	2	1	1	2
seetha	21	F	2296122011	3	1	1	2	1	2	2	2	0	1	2
elumalai	66	M	3290012010	1	2	2	1	5	3	2	2	0	1	2
Karunanidhi	28	F	3470062009	1	2	2	1	2	4	1	2	0	1	2
mohan	50	M	1786042009	3	1	2	2	1	3	2	1	0	1	2
arumugam	55	M	54122011	1	2	2	2	4	2	2	2	4	1	2
rajendran	45	M	2506122011	2	2	2	2	1	2	2	2	0	1	2
umapathy	43	M	1858122011	1	2	2	1	2	1	1	2	4	1	1
Ismail	40	M	2200122011	1	2	2	1	3	2	2	2	0	1	2
velmurugan	43	M	2608122011	1	2	2	2	1	3	1	2	0	1	2
ramesh	38	M	3543112011	2	2	2	2	1	3	2	2	0	1	2
Kuppan	55	M	3943122011	1	2	2	2	1	2	2	2	0	1	1
Janakiammal	65	F	3943122011	2	2	2	2	1	2	2	2	2	1	1
nirmala	35	F	3529102011	1	2	2	2	1	4	2	1	0	1	2
Rathinam	74	M	1799102010	1	2	2	1	2	3	2	2	0	1	2
Alagumuthaiya	60	M	12100122012	1	2	2	1	5	3	1	2	0	1	2
Rajendran	45	M	9860122012	3	1	1	2	3	2	2	2	0	1	2
umapathy	43	M	1858122011	3	2	2	2	1	3	2	2	0	1	2
ismail	40	M	2200122011	1	2	2	2	4	2	2	2	0	3	1
velmurugan	31	M	2608122011	1	2	2	2	1	2	2	2	0	1	2
ramesh	35	M	35431122011	1	2	2	2	1	4	2	2	2	1	2
kuppan	55	M	3943122011	1	2	2	1	3	3	2	2	0	3	2
janakiammal	65	F	3943122011	1	2	2	2	1	2	1	2	0	1	2

nirmala	35	F	3529102011	3	2	2	2	1	3	2	2	0	3	2
Rathinam	34	F	1799102010	1	2	2	1	2	2	2	2	0	1	2
alagumuthaiya	60	M	12100122012	3	2	2	2	3	2	2	2	0	1	2
rajendran	45	M	9860122012	1	1	1	1	4	2	2	2	2	3	2
rathinam	45	M	1223402011	1	2	2	2	1	3	2	2	0	1	2
alagesan	27	M	891012012	2	2	2	1	4	2	1	2	0	1	2
rajendran	45	M	986122012	1	1	1	2	1	4	2	2	0	1	2
kalaimani	30	M	3204622010	1	2	2	2	2	2	2	2	0	1	2
sumathi	25	F	1780042012	3	1	1	1	4	2	2	2	0	1	2
rama	43	F	2072042012	3	1	1	1	4	2	2	2	0	1	2
rajagopal	50	M	1631042012	1	2	2	1	2	3	2	2	2	1	2
perumal	60	M	3251062011	1	2	2	2	4	1	2	2	0	1	2
vimala	35	F	3296042012	2	2	2	2	1	3	1	2	0	1	2
alamelu	64	F	3289102011	1	2	2	2	1	3	2	1	0	1	1
dhamodaran	48	M	3305072008	2	1	1	1	2	2	1	2	0	1	1
arunadevi	25	F	4747022009	1	2	2	1	2	3	2	2	0	1	1
kumar	48	M	2483102011	1	2	2	2	1	3	2	2	0	1	2
vijaya	35	F	3761122011	1	2	2	2	2	2	1	2	0	1	2
marimuthu	40	M	352112005	1	2	2	1	1	2	2	2	0	1	2
gnanavel	31	M	352112005	1	2	2	1	2	1	2	2	2	1	2
narasaiyah	58	M	2818042003	2	2	2	1	1	3	1	2	0	1	2
gunasekar	43	M	2878022012	1	2	2	2	4	2	2	2	0	1	2
maheshwari	32	F	260032012	1	2	2	2	1	2	1	2	0	1	1
perumal	49	M	3579122007	1	2	2	1	1	2	1	2	0	1	2
aruldoss	30	M	3361122011	3	2	2	2	3	1	2	2	0	1	2
gnanavel	31	M	352112005	3	1	1	1	1	3	2	2	0	1	2
harikrishnan	49	M	4889082010	1	2	2	2	3	2	2	2	0	1	2
narayanan	36	M	1543032012	1	2	2	2	1	2	2	2	0	1	2
richard	45	M	4220032012	1	2	2	1	2	2	2	2	3	3	2
kumar	42	M	379042012	1	2	2	2	1	3	2	1	0	1	2
devan	38	M	3162032012	1	2	2	2	1	3	2	2	0	1	2
sampath	45	M	1008042012	1	1	1	2	1	3	2	2	0	1	2
kannan	47	M	3877052010	1	1	1	1	1	3	2	2	2	1	2

type of patient

smear negative -1
unconscious -2
no c/o sputum

gastric smear

positive-1
negative2

gastric culture

positive-1
negative-2

prior h/o ATT

present-1
nil-2

type of lesion

exudate -1
fibrocavity-2
cavity-3
consolidation-4

comorbities
nil-1
CKD-2
DM-2
LIVER DISEASE-3

Bronchoscopy
nil-1
positive-2

contact history
present-1
negative-2

HIV status

positive-1
negative2

sputum after ryle"s tube

positive-1
negative2